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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,304	02/08/2005	Ira Sanders	SAND3.0-002PCT/US	6448

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/524,304

Applicant(s)

SANDERS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10,11,14-34,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,10,11,14-34,56 and 57 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-6, 8, 10, 11, 14-34, 56 and 57 are pending.

Applicants' amendment filed December 28, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 3, 5, 16, 17, 20, 21, 24, 25 and 56 have been amended, claims 7, 9, 12, 13 and 45-49 have been cancelled, and a new claim 57 has been added.

Therefore, claims 1-6, 8, 10, 11, 14-34, 56 and 57 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-34, 45-49 and 56 under 35 U.S.C. 112, second paragraph, regarding lacking an essential step, or the term "whose level of glandular secretion is greater than desirable" or "the conditions", is withdrawn in view of applicant's amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 6 in the amendment filed December 28, 2006.

Withdrawn Claim Rejections - 35 USC § 102/103

3. The previous rejection of claims 3, 9, 45-47 and 49 under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suskine *et al.* (US 2005/0074466) is withdrawn in view of applicant's amendment to the claims, and applicants' cancellation of the claims in the amendment filed December 28, 2006.

Withdrawn Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1, 3, 5, 6, 9, 18, 19 and 28-34 under 35 U.S.C. 102(e) as being anticipated by Brin *et al.* (US 2002/0094339) is withdrawn in view of applicant's

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amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 6 in the amendment filed December 28, 2006.

5. The previous rejection of claims 46 and 56 under 35 U.S.C. 102(b) as being anticipated by Letessier (J. Dermatol. Treat. 10, 31-36 (1999)) is withdrawn in view of applicant's amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 6-7 in the amendment filed December 28, 2006.

Maintained Informalities

The disclosure is objected to because of the following informalities:

6. The specification recites a web address (e.g., page 14, line 33) which is impermissible. Appropriate correction is required.

Applicants did not respond to the objection.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 29-34 are indefinite because of the use of the term "the botulinum toxin comprises botulinum toxin B". The term cited renders the claim indefinite, it is not clear how the botulinum toxin, which is a compound, can comprise another compound, i.e., botulinum toxin B.

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Response to Arguments

Applicants indicate that the toxin administered must contain any one of the alphabetically labeled botulinum toxins but may contain other toxins within the genus, hence the term "comprising" is justified in both meanings of the term (page 6 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because the specification does not indicate the botulinum toxin administered contains more than one sero-type of botulinum toxin. Furthermore, the botulinum toxin cited in the claim is not plural.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-2, 4-6, 8, 10, 11, 14-34, 56 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suskine *et al.* (US 2005/0074466, priority date July 27, 2001) as evidenced by Sanders *et al.* (US2005/0220820 A1).

Suskine *et al.* teach the use of botulinum toxin (i.e., serotype A, B, C, D, E, F, G) to treat acne, which the pathology centers on the pilosebaceous follicle comprising the sebaceous gland, the follicle (pore) and the vellus hair (paragraph [0005]), and the treatment may be repeated periodically to inhibit the recurrence of acne, typically at intervals between about 3 months and about 6 months, preferably about once every 4 months (paragraph [0036]; claims 1-2, 26-34). For example, a female patient with severe cystic acne is injected intracutaneously with botulinum toxin A in her forehead, chin and cheek/nasolabial fold area approximately one every six months. After the treatment, she experienced a complete resolution of her acne, and the injections are spaced approximately 1.5 cm apart from one another, and the dose per injection site is about 2.5 U (Example 1; claims 5, 8, 14, 15, 20-24). Since the reference also teaches botulinum toxin can be applied to the skin topically as a cream or in other forms (paragraph [0098]; claim 4), or can be injected subcutaneously (see claim 5 of US 2005/0074466; claim 6), it would be obvious that botulinum toxin A would be injected subcutaneously at the same sites using the same dosage as Example 1 (claims 10, 11, 16-19 and 25). Since acne is a pathology of the skin pore having excess sebum production within pilosebaceous glands, which result in an enlarged and

obstructed sebum gland, as evidenced by Sanders et al. (US2005/0220820 A1; paragraphs [0043]-0045)), the treatment of patients having acne with topical administration, or subcutaneous or intracutaneous injection of botulinum toxin would inherently reduce secretions from pilosebaceous glands, decrease the skin pore size of the patients and smooth the fine wrinkles (claims 56 and 57). The term "cutaneous" is equivalent to "dermal", see page 11, line 31-32 of the specification.

Response to Arguments

Applicants indicate that there is no mention in this reference of reduction of excess secretion from the (sebaceous) holocrine gland, neither is there any suggestion that the application of botulinum toxin to treat acne is in any way related to the reduction of excess glandular secretion. Finally, applicant is not able to find any basis in the reference for the Examiner's postulate with respect to claims 45-47, 49 (now cancelled) and 56 (as amended) (page 6 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. Although the reference does not indicate the administration of botulinum toxin reduces excess secretion from the (sebaceous) holocrine gland, decreases the skin pore size of the patients and smoothes the fine wrinkles, the reference teaches using the same method steps as the claimed method in the treatment of a patient with a condition such as acne which is related to excess sebum production within pilosebaceous glands, which result in an enlarged and obstructed sebum gland, as evidenced by Sanders et al. (US2005/0220820 A1; paragraphs [0043]-0045)). Therefore, the administration of botulinum toxin would inherently reduce secretions from holocrine glands, decrease the skin pore size of

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the patients and smooth the fine wrinkles.

Claim Objections

10. Claim 3 is objected to because the claim is dependent from a rejected claim.

Conclusion

11. Claims 1-2, 4-6, 8, 10, 11, 14-34, 56 and 57 are rejected; and claim 3 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

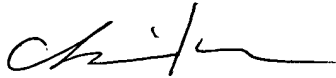
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

March 21, 2007